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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,381	03/19/2004	Scott Edward Osborne	7892C	7237

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,381

Applicant(s)

OSBORNE ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-14,16,17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-14,16,17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 8-22-05 is acknowledged.

Claims 1-5, 7-14, 16, 17, 19 and 20 are pending in the instant application.

Response to Arguments

In view of the amendment presented on 8-22-05, the rejection of record has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 103

1. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,802 to Johansson et al (Johansson) in view of US 5,614,178 to Bloom et al (Bloom).

Johansson teaches topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). The components urea, lactic acid, paraffin liquid and polyoxyethylene-2-stearyl-ether read on the claimed skin protectant, pH control agent, and barrier protectant and release agent respectively. Johansson teaches skin composition containing chitosan in the form of cream. Johansson fails to teach the claimed release agent with the claimed HLB value, specific nonionic surfactants, and the additional skin care active agents.

Bloom teaches compositions for topical application containing a high molecular weight polymer, a non-ionic surfactant having a high HLB (above 6) for enhanced

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penetration of through skin (See col. 3, lines 7-16). Bloom teaches the composition in the form of cream (col. 14, last line). Bloom teaches a number of drugs or active agents, that are water –soluble, including ascorbic acid i.e., vitamin C (col. 9, lines 42, col. 4, lines 56-68; cols. 5-9), non-ionic surfactants with HLB above 3 (col. 11, lines 48 through col. 12), which includes the surfactants of instant claims 7-9. Bloom teaches humectants, fatty alcohols and other ingredients in col. 14 and also in examples. The lotions and creams of Bloom (col. 14, last line) read on semi-solid composition of the instant composition. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the non-ionic surfactants (having the claimed HLB value) of Bloom in the topical composition of the Johansson containing chitosan and other active agents because Bloom teaches that topical administration of active agents using the claimed surfactants as penetration enhancing agents (release agents) to administer the active agents in both low and high amounts. Thus, both Bloom and Johansson are directed to topical application of skin treating agents and accordingly a skilled artisan would have expected to achieve an effective transdermal penetration of the chitosan containing composition of Johansson, even in low amounts.

2. Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,802 to Johansson et al (Johansson) in view of US 5,614,178 to Bloom et al (Bloom) as applied to claims 1-5 and 7-13 above and further in view of EP 297828.

Neither Bloom nor Johansson explicitly state “an absorbent article” as claimed.

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EP teaches EP teaches a medicated dressing or bandage (absorbent, woven as well as nonwoven) for topical application of bioactive agents in the form of a fabric or a pad and is coated or impregnated with the active ingredient in a soft or waxy vehicle, such that the active is released to the skin. The vehicle of EP comprises natural wax, petrolatum or other synthetic waxes; and the active agent may be an antibacterial or anti-inflammatory agent or anesthetic (page 3). The bandage of EP is made of a nonwoven or woven fabric (page 3).

Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to employ a pad, bandage to apply the composition of Johansson (containing the release surfactants of Bloom) because EP suggests that topical delivery of medicaments can be targeted precisely to the desired location and an efficient release of the active agents through the skin occurs upon local application and at the same time provides a sterile covering over the area of application.

3. Claims 14, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,517,848 to Huard et al (Huard) in view of US 6,562,802 to Johansson et al (Johansson) or in view of US 4,528,283 to Lang.

Huard teaches absorbent articles such as diapers, incontinence devices having an absorbent surface and a skin irritant sequestering agent disposed therein together with other skin benefit agents. Huard teaches that bodily fluids comprises enzymes that cause irritation to the skin and that the addition of the irritation sequestering agents to the absorbent article results in binding the enzymes and preventing them from

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damaging skin, usually associated with diaper rash or other incontinence devices (col. 2). Huard also teaches addition of skin benefit agents prevent the absorption of fecal materials through skin and teaches a number of skin benefit agents (col. 5-8). While Huard lists the claimed chitosan, release agents, barrier protectants etc., among the benefit agents, Huard fails to explicitly teach the claimed composition.

Johansson teaches topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). Johansson teaches chitosan and its derivatives for its skin protecting (against irritants) properties and suggests including the same in topical compositions together with other lipophilic skin-protecting substances (col. 7-8 and col. 11-12).

Lang teaches chitosan and its derivatives for their skin protecting, moisturizing, skin tonic as well as moisture holding properties (col. 3) when added to skin treating compositions. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use chitosan or its derivatives (Johansson, Lang and Huard) together with other lipophilic skin benefit agents (including the claimed barrier protectants, surfactants etc) described by Johansson and also Huard in the skin protecting composition applied on to the absorbent article of Huard because Johansson and Lang suggest chitosan for its skin protective effects from skin irritating substances and other skin benefit agents for preventing the irritating substances to penetrate through skin by forming a barrier protection.

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4. Applicants stated in their previous response (dated 2-3-05) that a terminal disclaimer would be filed upon finding an allowable subject matter. Since no claim is allowed at this time, the following double patenting rejection is maintained:

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,716,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims directed to an article and a method of effectively delivering one or more skin care actives recite specific active agents and release agents, which are encompassed by the broadly recited release agents and skin care actives of the instant claims. The specific release composition of the patented claims anticipates the broad genus claimed in the instant invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
October 25, 2005


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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